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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/763,197 | 01/26/2004 | Alex Shakhov | MR2767-3 | 6429 |

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| EXAMINER | |
|---|---|
| BELYAVSKYI, MICHAIL A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

| NOTIFICATION DATE | DELIVERY MODE |
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| 01/27/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/763,197 | SHAKHOV ET AL. | |
| | Examiner | Art Unit | |
| | Michail A. Belyavskyi | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-3 and 5-32* is/are pending in the application.

4a) Of the above claim(s) *7-9,11-15 and 19-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,10 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's petition for revival of an application for patent under unintentional provision of 37 C.F.R. 1.137(b) has been granted.

2. Claims 1-3, 5-32 are pending.

3. Claims 7-9, 11-15 and 19-32 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

*Claims 1-3, 5, 6, 10 and 16-18 read on a method for treating a cytopathological disease, wherein said disease is cancer are under consideration in the instant application.*

In view of the amendment, filed 06/05/08 the following rejections remain

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

5. Claims 1-3, 5, 6, 10 and 16-18 stand rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,199,942 (IDS) for the same reasons set forth in the previous Office Action, mailed on 03/21/07.

Applicants arguments filed on 06/05/08 have been fully considered but have not been found convincing.

Applicant asserts that : (i) though US Patent '942 provide a method for autologous hematopoietic cell transplantation, US Patent' 942 does not teach a method where introducing a stem cell growth stimulating agent into the donor prior to harvesting and does not teach that the introducing specimen is not purge prior to re-infusion.

Contrary to Applicant's assertion it is the Examiner position that US Patent '942 does teach administering stem cell growth stimulating agent into the donor prior to harvesting. Applicant's attention is respectively drawn , for example, on column 3. It is explicitly stated that stem cell growth stimulating agent can be used *in vivo* to induced mobilization hematopoietic stem cell into peripheral blood. Hematopoietic progenitor cells harvested further from peripheral blood can be used for hematopoietic rescue therapy. In other words, US Patent '942 teaches administering stem cells growth stimulating factors prior to harvesting hematopoietic progenitor cells.

With regards to the comments that US Patent'942 does not teach that the introducing specimen is not purge prior to re-infusion.

Contrary to Applicant's assertion, nowhere US Patent'942 teaches that re-infused stem cells should be purged prior to administering back to the patient.

US Patent '942 teaches a method for treating cancer comprising harvesting a biological specimen containing stem cells from the body, storing said biological specimen using cryo-preservation for a predetermined period and re-introducing said stem cell in therapeutic amount in the donor ( see entire document, Abstract in particular). US Patent '942 teaches that said biological specimen is peripheral blood or bone marrow ( see column 3 in particular). US Patent' 942 teaches a step of introducing a stem cell growth stimulating agent into donor prior to the harvesting ( see column 4 in particular).

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The reference teaching anticipates the claimed invention.

The following new ground of rejections is necessitated by the amendment filed 06/05/08

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-3, 5, 6, 10 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,569,427 in view of newly cited US Patent 5,637,323 and US Patent 6,162,427

US Patent '427 teaches a method for treating cancer comprising harvesting a biological specimen containing stem cells from the body, storing said biological specimen using cryo-preservation for a predetermined period and re-introducing said stem cell in therapeutic amount in the donor ( see entire document, Abstract in particular). US Patent '427 teaches that said biological specimen is peripheral blood or bone marrow ( see column 12 in particular).

US Patent' 427 does not explicitly teach introducing a stem cell growth stimulating agent into the donor prior to harvest.

US Patent ' 323 teaches the method of mobilization of hematopoietic stem cells into the peripheral blood by administering a stem cell growth stimulating agent( see entire document Abstract in particular). US Patent' 323 teaches that administering a stem cell growth stimulating agent into a donor prior of isolating hematopoietic stem cells results in increasing in number of isolated hematopoietic stem cells from said donor. US Patent ' 323 teaches that isolated biological specimen containing an enrich number of hematopoietic stem cells can be used immediately or stored using cryopreservation techniques for further clinical usage ( see overlapping columns 6 and 7 and 29 in particular). US Patent '323 further teaches that said isolated biological specimen containing an enrich number of hematopoietic stem cells administered directly to the recipient without been purged ( see column 6, lines 29-42 and in particular).

US Patent' 427 teaches the method of mobilization of hematopoietic stem cells into the peripheral blood by administering a stem cell growth stimulating agent( see entire document Abstract in particular). US Patent' 427 teaches that administering a stem cell growth stimulating agent into a donor prior of isolating hematopoietic stem cells results in increasing in number of isolated hematopoietic stem cells from said donor.

All the claimed elements were known in the prior art and one skill in the art could have combine the elements as claimed by known methods with no change in their respective function and the combination would have yield predictable results to one of ordinary skill in the art at the time of the invention ( see *KSR International Co v Teleflex Inc*., 550U.S.-, 82 USPQ2d 1385, 2007).

Thus it would have been obvious to one of the ordinary skill in the art at the time the invention was made to introduce a stem cell growth stimulating agent into the donor prior to harvest said cells with a reasonable expectation of success because the prior art suggests that administering a stem cell growth stimulating agent into the donor prior to harvest results in increasing in number of isolated hematopoietic stem cells from said donor.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. No claim is allowed .

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/ 272-0840 The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571/ 272-0878.
The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michail A Belyavskyi/
Primary Examiner, Art Unit 1644